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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/460,107

12/13/1999

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2034

21091

7590

12/17/2002

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EXAMINER

LU, FRANK WEI MIN

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 12/17/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/460,107

Applicant(s)

Astle

Examiner

Frank Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 1, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above, claim(s) 1-11 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 29-32 is/are allowed.
- 6) ☒ Claim(s) 12-23 and 27 is/are rejected.
- 7) ☒ Claim(s) 24-26 and 28 is/are objected to.
- 8) ☐ Claims are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Dec 13, 1999 is/are a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action November 23, 2001 has been entered as Paper No: 13 and petition filed on April 1 was granted on August 26, 2002. The claims pending in this application are claims 1-32 with claims 1-11 withdrawn from consideration as the result of the restriction requirement. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn.

Election/Restriction

2. This application contains claims 1-11 drawn to an invention nonelected with traverse in Paper No. 4. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Specification

5. The disclosure remains objected to because of the following informalities: Both Application Serial Nos. 09/271,050 and 09/198,018 are pending application. No patent has issued for these cases. The applicant is advised to delete US Patent No. and issued date on line 4, 5, and 8 of page 2 of subject application.

Appropriate correction is required.

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Response to Arguments

In page 5, fifth paragraphs of applicant's remarks, applicant suggested that "if a Notice of Allowance in this application is issued before that information becomes available, the Examiner is authorized to delete that material by Examiner's Amendment at that time".

This argument have been fully considered and have not been found pervasive since the cases 09/271,050 or 09/198,018 have not been issued. The examiner agrees delete that material by Examiner's Amendment if US Patent Nos. for Application Serial Nos. 09/271,050 and 09/198,018 are not available when this instant applicant is ready to allow.

Claim Rejections - 35 U.S.C. § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 12-15, 17-23, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Danssaert *et al.*, (US Patent No. 5,779,981, published on July 14, 1998).

Danssaert *et al.*, teach thermal cyler including a temperature gradient block. As shown in Figure 3, in PCR, the first, second, and third blocks were programmed to be maintained at a temperature range of between about 25 °C to 99 °C, and were used for denaturing, annealing and extension respectively. The fourth block (made by metal, see column 5, first paragraph) was generally maintained at between 4 and 25 °C (see column 6, last paragraph). The reaction

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mixtures could be moved between gradient blocks (see column 3, eight paragraph) using RoboCycler system (see Staratagene catalog, pages 256 and 257, 1994) and reactions were carried out in 500 μ l eppendorf tubes (see column 7). Note that: (1) a plurality of reaction wells in the blocks were considered as index patterns of reagent wells on a continuous basis as recited in claim 12 since each well had its own number wherein the numbers were on a continuous basis; (see Figure 1); (2) different gradient blocks with different temperatures were considered as heat transfer stations as recited in claim 12; and (3) a reagent well and 500 μ l eppendorf tube inside of the reagent well were considered as a sealed reagent well as recited in claim 13 with the limitations of claims 14-17, and 19; (4) the addition of PCR reagents from different stock solutions into the eppendorf tubes after the eppendorf tubes were inserted into the wells of a metal block was considered to have the limitations of claims 13, 21, and 22 and stock solutions were be refilled as recited in claim 23; (5) RoboCycler system (see above) was considered as electronic stepper drive as recited in claim 18; and (6) the cap of eppendorf tubes was considered to be peelable as recited in claim 27.

Therefore, Danssaert *et al.*, teach all limitations recited by claims 12-15, 17-23, and 27.

Response to Arguments

In page 5, last paragraph bridging to page 6, second paragraph of applicant's remarks, applicant argued that "the base claim is obviously not anticipated by the reference" since "the device /process of Danssasert et al. requires that all three heat transfer stations are required for one amplification step. Applicant's claimed invention is directed to a PCR processing apparatus which provides one amplification at each individual heat transfer step."

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This argument has been fully considered and has not been found pervasive toward the withdrawal of the rejection. Although claim 12 has the limitation “a PCR processing apparatus which provides one amplification at each individual heat transfer step”, this claim is a “means or step plus function” claim. Since Danssaert *et al* taught different gradient blocks with different temperatures in a PCR processing apparatus, which were considered as heat transfer stations, and these heat transfer stations could perform the function (a amplification step) as recited in claim 12, the examiner considered that Danssaert *et al.*, taught a PCR processing apparatus which provides one amplification at each individual heat transfer step. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

5. Claims 12-17, 19, 21-23 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Mitsuhashi *et al.*, (US Patent No. 5,545,528, published on August 13, 1996).

Mitsuhashi *et al.*, teach PCR. In experiment 3, single stranded cDNA was mixed with each of the sense and antisense primers, PCR buffer and Taq polymerase (Promega) in each well of a 96 well microtiter plate. PCR was carried out either polypropylene tubes, or polypropylene plates (Coster, Nunc). For tubes, PCR was carried out in thermal cycles (model 480. Perkin-Elmer Cetus, Norwalk, Conn.). For Nunc plates, PCR was done in thermal cycles (CMJ Research). For Coster plates, PCR was performed by manually soaking into 3-8 different water bathes (see column 12). Note that: (1) 96 wells in the microtiter plate was considered as index patterns of reagent wells on a continuous basis as recited in claim 12 with the limitations of claims

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12, 14-17, and 19 since each well had its own number wherein the numbers were on a continuous basis;; (2) different water bathes with different temperature were considered as heat transfer stations as recited in claim 12; (3) the mixing of PCR reagents by pipetting different reagents from their stock solutions was considered to have the limitations of claims 13, 21 and 22 and stock solutions could be refilled as recited in claim 23; and (4) the cover of microtiter plate was considered as a peelable sealer of the reagent wells as recited in claim 27.

Therefore, Mitsuhashi *et al.*, teach all limitations recited by claims 12-17, 19, 21-23, and 27.

Response to Arguments

In page 5, last paragraph bridging to page 6, second paragraph of applicant's remarks, applicant argued that: "[T]he examiner is respectfully reminded that it is well settled that claims are to be interpreted in light of the entire disclosure." since "[C]laim 12 includes the limitation that patterns of wells are indexed on a continuous basis through a plurality of individual heat transfer stations, at each of which stations the patterns are subject to a unique temperature change resulting in one amplification step."

This argument has been fully considered and has not been found persuasive toward the withdrawal of the rejection. Although claim 12 has the limitation "a PCR processing apparatus which provides one amplification at each individual heat transfer step", this claim is a "means or step plus function" claim. Since Mitsuhashi *et al.*, taught different gradient blocks with different temperatures in a PCR processing apparatus, which were considered as heat transfer stations, and these heat transfer stations could perform the function (a amplification step) as recited in claim 12,

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the examiner considered that Mitsuhashi *et al.*, taught a PCR processing apparatus which provides one amplification at each individual heat transfer step. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Claims 24-26 and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. Claim 19-32 are allowed over the prior art in the record.

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9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms. Chantae Dessau, whose telephone number is (703) 605-1237.

Frank Lu
December 13, 2002

ELLW
Ethan Whewort
Primary Examiner